IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION; STATE OF NEW YORK; STATE OF CALIFORNIA; STATE OF ILLINOIS; STATE OF NORTH CAROLINA; STATE OF OHIO; COMMONWEALTH OF PENNSYLVANIA; and COMMONWEALTH OF VIRGINIA, Plaintiffs, v. VYERA PHARMACEUTICALS, LLC; PHOENIXUS AG; MARTIN SHKRELI, individually, as an owner and former officer of Vyera Pharmaceuticals, LLC and Phoenixus AG (formerly known as Turing Pharmaceuticals, LLC and Turing Pharmaceuticals AG); and KEVIN MULLEADY, individually, as an owner and director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC Defendants.	Case No. 1:20-cv-00706-DLC

DEFENDANT MARTIN SHKRELI'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO STAY ORDER FOR PERMANENT INJUNCTION PENDING APPEAL

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I. INTRODUCTION

On February 4, 2022, the Court issued its Judgment, Part II of which bans Defendant Martin Shkreli from, among other things, participating in the pharmaceutical industry for life (the "permanent injunction"). The permanent injunction should be stayed pending appeal of the Court's Judgment and January 14, 2022 Opinion and Order (ECF 865, the "Opinion") pursuant to Federal Rule of Civil Procedure 62(d).[1] The standards for a stay are met here.

First, Mr. Shkreli is likely to succeed on the merits of his anticipated appeal. Respectfully, the Court made several errors in its ruling, including the following:

a) The Court abused its discretion in banning Mr. Shkreli from the pharmaceutical industry for life. The injunction is overbroad and punitive, preventing Mr. Shkreli from engaging not only in conduct that the Court held to be unlawful, but also lawful conduct that is totally unrelated to the conduct alleged in this case. The injunction also violates Mr. Shkreli's First Amendment rights and is impermissibly vague in violation of Federal Rule of Civil Procedure 65(d).

b) The Court erred in holding that Vyera's supply and distribution contracts had anticompetitive effects. The Court applied the wrong standard for analyzing competitive effects and erred in holding that plaintiffs had satisfied their burden of proving that Vyera's contracts actually caused harm.

c) The Court misapplied the equitable standards in *Liu v. SEC*, and thus erred in holding Mr. Shkreli jointly and severally liable.

d) The Court erred in holding that plaintiffs had satisfied their burden of proving that the relevant product market in which to analyze the competitive effects is FDA-approved pyrimethamine. The record shows clearly that TMP-SMX, Atovoquone, and compounded pyrimethamine are substitutes for Daraprim that should be included in the relevant product market.

Second, Mr. Shkreli will suffer irreparable harm if the stay is not granted. Banning Mr. Shkreli from any involvement in the industry to which he has devoted most of his working life constitutes irreparable harm.

[1] Contemporaneously with the filing of this motion, Mr. Shkreli is filing a separate motion to stay the monetary relief portion of the Judgment.

Third, the stay will not substantially injure any interested parties, as Vyera is subject to an order barring it from engaging in the challenged conduct either with or without Mr. Shkreli's participation and the CREATES Act prevents any risk of harm to generic companies going forward.

Fourth, the public interest will be served by a stay because it will allow Mr. Shkreli to return to researching cures for rare diseases.

II. PROCEDURAL BACKGROUND

On January 27, 2020, the FTC and New York Attorney General ("NYAG") filed the Complaint that commenced this action. ECF 4. On April 14, 2020, the remaining plaintiff states joined the case, and collectively, the plaintiffs filed the Amended Complaint. ECF No. 86.

The Court held trial from December 14-22, 2021. On January 14, 2022, the Court issued its Opinion and Order (ECF 865, the "Opinion"), holding Mr. Shkreli liable on each of plaintiffs' claims. The Court held that Vyera[2] maintained monopoly power in a relevant product market of FDA-approved pyrimethamine sold in the United States. Opinion, at pp. 100-108. The Court also held that Vyera engaged in anticompetitive conduct by entering into exclusive supply agreements for the supply of pyrimethamine – the active pharmaceutical ingredient ("API") used to manufacture Daraprim – and a specialty distribution system for the distribution of Daraprim. The Court held that Mr. Shkreli was individually, and jointly and severally, liable for Vyera's alleged anticompetitive conduct because he "conceived of, implemented, maintained, and controlled Vyera's anticompetitive and monopolistic scheme," despite Mr. Shkreli's departure from the Company in January 2016 and incarceration since 2017. Opinion at p. 120.

[2] We will refer to Vyera and Phoenixus collectively as "Vyera" or "the Company."

The Court ordered plaintiffs to present to Mr. Shkreli a proposed judgment by January 24, 2022, for Mr. Shkreli to provide to plaintiffs his objections to the proposed judgment by January 28, 2022, and for plaintiffs to file the proposed judgment with Mr. Shkreli's objections on January 28, 2022. ECF 866. Pursuant to the order, Mr. Shkreli submitted his objections to plaintiffs on January 28, 2022, which plaintiffs filed with their proposed judgment on the same day. ECF 867. Mr. Shkreli's objections included constitutional objections, as well as objections based on the over breadth and vagueness of certain provisions of plaintiffs' proposed judgment. On February 4, 2022, following briefing on the objections, the Court issued its Opinion and Order on Mr. Shkreli's objections (ECF 875), and entered an Order for Permanent Injunction and Equitable Monetary Relief. ECF 876 (the "Judgment").

The Court's Opinion and Order on Mr. Shkreli's objections (ECF No. 875) either did not address, disregarded, or summarily dismissed each of Mr. Shkreli's objections. With the exception of a few minor changes, the Court accepted plaintiffs' proposed judgment. Despite the fact that this is a civil antitrust case involving two specific types of allegedly anticompetitive agreements, the Judgment broadly imposes a lifetime ban on Mr. Shkreli "from directly or indirectly participating in any manner in the pharmaceutical industry." Judgment at p. 5. In addition, the Judgment misapplies the equitable principles of joint and several liability and set-off, and orders Mr. Shkreli to pay the full amount of equitable monetary relief of $64.6 million within 30 days of the entry of the Judgment, despite the fact that Mr. Shkreli never received a salary from the Company, did not profit at all from the anticompetitive conduct alleged in the Amended Complaint – nearly all of which was pursued and implemented by other Company employees after Mr. Shkreli resigned from the Company and was incarcerated – and despite the fact that the Company and Mr.

Mulleady settled the claims against them for up to $40 million, $10 million of which has already been paid to plaintiffs.

Mr. Shkreli intends to file a notice of appeal with the United States Court of Appeals for the Second Circuit, and now files this motion to stay the Judgment pending the outcome of that appeal.

III. ARGUMENT

A. Legal Standard for Granting a Stay Pending Appeal

A district court may "suspend, modify, restore, or grant an injunction" while an appeal from such an order is pending. Fed. R. Civ. P. 62(d). When deciding whether to grant a stay pending appeal, district courts look to the following factors:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

S.E.C. v. Citigroup Global Markets, Inc., 673 F.3d 158, 162 (2d Cir. 2012) (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)). The four stay factors "operate as a 'sliding scale,' where '[t]he necessary "level" or "degree" of possibility of success will vary according to the court's assessment of the other stay factors.'" *In re Electronic Books Antitrust Litig.*, Nos. 11-md-2293 & 12-cv-3394, 2014 WL 1641699, at *4 (S.D.N.Y. Apr. 24, 2014) (Cote, J.) (quoting *Thapa v. Gonzales*, 460 F.3d 323, 334 (2d Cir. 2006)).

B. Mr. Shkreli is Likely to Succeed on the Merits in the Appeal

A likelihood of success on the merits requires "more than a mere possibility of relief." *Nken v. Holder*, 556 U.S. 418, 434 (2009). The showing required is akin to "a substantial possibility" of success on appeal. *Mohammed v. Reno*, 309 F.3d 95, 101 (2d Cir. 2002). Here, there is a substantial possibility that Mr. Shkreli's appeal will succeed on the merits for at least the

following four reasons: (1) the Court abused its discretion in issuing a permanent injunction that is not narrowly tailored to the conduct at issue; (2) the Court erred in holding that Vyera's agreements caused anticompetitive effects; (3) the Court erred in holding Mr. Shkreli jointly and severally liable; and (4) the Court erred in holding that plaintiffs had met their burden to prove the relevant product market.

1. The Court Abused its Discretion in Issuing a Permanent Injunction That is Not Narrowly Tailored to the Conduct at Issue.

Mr. Shkreli is likely to succeed on appeal in demonstrating that the Court erred in issuing a permanent injunction that is overly broad and not narrowly tailored to the conduct at issue. As the Court held in its opinion concerning Mr. Shkreli's objections to plaintiffs' proposed order, "injunctive relief should be narrowly tailored to fit specific legal violations." ECF 85, at p. 3 (quoting *City of New York v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 144 (2d. Cir. 2011)). The Court also held that an injunction is overbroad "when it seeks to restrain the defendants from engaging in legal conduct, or from engaging in illegal conduct that was not fairly the subject of litigation." ECF 85, at p. 4 (quoting *Mickalis*, 645 F.3d at 145). A "district court's issuance of a permanent injunction [is reviewed] for abuse of discretion." *Mickalis*, 645 F.3d at 142. The injunction issued in this case will not survive review under that standard.

The United States Supreme Court has held that it "will strike from an injunction decree restraints upon the commission of unlawful acts which are thus dissociated from those which a defendant has committed." *NLRB v. Express Pub. Co.*, 312 U.S. 426, 436 (1941) ("[T]he mere fact that a court has found that a defendant has committed an act in violation of a statute does not justify an injunction broadly to obey the statute and thus subject the defendant to contempt proceedings if he shall at any time in the future commit some new violation unlike and unrelated to that with which he was originally charged"). In *NLRB*, the Supreme Court reversed the

judgment and modified the injunction, holding that an appropriate order "would go no further than to restrain respondent" from the specific illegal conduct found in the case, and that "respondent's past conduct . . . would be effectively prevented by the prohibition of such an order without drawing it so broadly as to forbid all other" unrelated unlawful conduct. *NLRB*, 312 U.S. at 438. The Supreme Court has similarly modified an injunction obtained by the Federal Trade Commission because it was "too broad," by narrowing it to prohibit only the specific violations and tactics/agreements found by the Court to have been committed. *See FTC v. Beech-Nut Packing Co.*, 257 U.S. 441, 456 (1922).

Consistent with these holdings of the Supreme Court, the Second Circuit held in *Mickalis* that a properly drawn "injunction may not 'enjoin "all possible breaches of the law."'" *Mickalis*, 645 F.3d at 144 (citing *John B. Hull, Inc. v. Waterbury Petroleum Prods., Inc.*, 588 F.2d 24, 30 (2d Cir. 1978) (quoting *Hartford-Empire Co. v. United States*, 323 U.S. 386, 410 (1945))). Thus, the Second Circuit vacated the injunctive relief granted by the district court in that case because it sought to prohibit not only the specific "kind of illegal practice identified in the City's amended complaint," but other, unidentified illegal types of practices, as well. *Mickalis*, 645 F.3d at 145.

In addition to vacating injunctions that go too far in restraining *illegal* conduct that is not alleged in the complaint, the Second Circuit, and courts within the Second Circuit, have often vacated or modified overly broad injunctions that restrain purely *legal* conduct. *See, e.g., Shakhnes v. Berlin*, 689 F.3d 244, 257 (2d Cir. 2012) (vacating injunction and holding that "[a]n injunction is overbroad when it restrains defendants from engaging in legal conduct"); *SP Special Opportunities, LLC v. LightSquared, Inc. (In re LightSquared, Inc.)*, 539 B.R. 232, 246 (S.D.N.Y. 2015) (vacating injunction because it "creates a serious risk of chilling ordinary commercial activity" and because "[m]arket participants should not be prohibited from . . . competing in the

marketplace in an otherwise lawful manner"); *New York v. Shinnecock Indian Nation*, 560 F. Supp. 2d 186, 191 (E.D.N.Y. 2008) (narrowing the scope of the proposed injunction and listing numerous cases in support of "Second Circuit precedent vacating such overbroad injunctions").

Here, plaintiffs alleged, and the Court found, that Mr. Shkreli was liable for civil antitrust violations as a result of his participation in two specific types of commercial agreements – namely, exclusive supply agreements for API and limited distribution agreements for the finished pharmaceutical product, Daraprim. Rather than fashion an injunction based on the conduct that was the subject of the litigation, the Court issued a permanent injunction "bann[ing] and enjoin[ing] [Mr. Shkreli] for life from directly or indirectly participating in any manner in the pharmaceutical industry." ECF 876, p. 5. The Court's injunction not only prohibits Mr. Shkreli from participating in unknown illegal conduct not alleged or at issue in the case, but it prohibits Mr. Shkreli from participating in legal conduct as well – *i.e.*, "competing in the marketplace in an otherwise lawful manner" – for life. *In re LightSquared, Inc.*, 539 B.R. at 246. "Remedies intended to punish culpable individuals" are "issued by courts of law, not courts of equity," and the Court's role in this case is that of an equity court. *See Tull v. United States*, 481 U.S. 412, 422 (1987). The Court's overly broad injunction, reaching conduct far beyond the conduct at issue in this case, is punitive in nature and outside the scope of the Court's authority.

Indeed, in response to Mr. Shkreli's objections to the over breadth of the injunction and violation of his First Amendment rights, the Court held that Mr. Shkreli's "violations of the antitrust laws have lost for him the right to speak publicly about the pharmaceutical industry when such speech is uttered to influence the management or business of a Pharmaceutical Company" – no matter what the subject, even if it relates to industry concerns that were not at issue in this case, such as concerns about patient confidentiality, cybersecurity, or human resources. ECF 876, p. 8.

Additionally, the injunction states that Mr. Shkreli cannot invest in a Pharmaceutical Company, research or develop novel treatments or drugs for a Pharmaceutical Company, or "indirectly influence or control the management or business of any Pharmaceutical Company," as that term is broadly and vaguely defined. ECF 876, p. 5. This far-reaching injunction, restraining Mr. Shkreli from engaging in *any conduct*, whether legal or illegal, in the pharmaceutical industry, goes well beyond the specific alleged anticompetitive agreements in which the Court found Mr. Shkreli to have participated. As such, the injunction goes far beyond the boundaries imposed by the Supreme Court, the Second Circuit, and courts within the Second Circuit.[3]

Another reason that Mr. Shkreli is likely to succeed on the merits is that the Court's Judgment is impermissibly vague pursuant to Fed. R. Civ. P. 65(d), *i.e.*, it is not "sufficiently clear to [Mr. Shkreli to know] exactly what [is] required of [him]." *Sanders v. Air Line Pilots Asso., Int'l*, 473 F.2d 244, 247 (2d Cir. 1972); *see also Schmidt v. Lessard*, 414 U.S. 473, 476 (1974) (vacating injunction and holding that "basic fairness requires that those enjoined receive explicit notice of precisely what conduct is outlawed"); *SEC v. Lorin*, 76 F.3d 458, 461 (2d Cir. 1996) (vacating permanent injunction because it lacked "the requisite specificity" to allow an enjoined party to know what is required of him). For example, the definition of "pharmaceutical company" is both overbroad and vague. Within the defined term of "pharmaceutical company," both "commercialization" and "marketing" are undefined terms that could be interpreted to include restrictions on conduct that is far removed from the anticompetitive conduct found by the Court.

[3] The Court based its broad injunction against Mr. Shkreli, in part, on its findings regarding Mr. Shkreli's activities at another company he founded, Retrophin. *See* ECF 865, p. 124 ("Without a lifetime ban, there is a real danger that Shkreli will engage in anticompetitive conduct within the pharmaceutical industry again."). The Court found that Mr. Shkreli's conduct at Retrophin involved the "same anticompetitive business model" as at Vyera. *Id.* Thus, the Retrophin conduct could support, at most, an injunction tailored to the specific conduct at issue in this case – entering into exclusive API agreements and distributing pharmaceuticals through specialty distribution – not a lifetime ban against *any participation* in the pharmaceutical industry. *See NLRB*, 312 U.S. at 438 ("respondent's past conduct . . . would be effectively prevented by the prohibition of such an order without drawing it so broadly as to forbid all other" unlawful conduct").

It is unclear, for example, whether Mr. Shkreli would be foreclosed from working in any capacity for an advertising agency that markets pharmaceuticals, even if his job has nothing to do with pharmaceuticals. The reaches of such a broad and vague definition are unlimited and unknown, and Mr. Shkreli would be in danger of unwittingly violating such an order by engaging in lawful conduct that is unrelated to the conduct at issue in this case.

The inclusion of the vague "qualified employment" definition does not resolve the issue, as it requires Mr. Shkreli, before he accepts employment, to undertake a subjective analysis of whether his potential employer is "***primarily*** involved in the research, Development manufacture, commercialization, or marketing of Drug Products or APIs and whose gross revenues from this activity ***accounts for less than 10% of the total gross revenues of the Pharmaceutical Company***." Judgment, Section I.N (emphasis added). It is unclear how Mr. Shkreli is expected to approach potential employment with a company, such as Costco, Walgreens and CVS, that market and sell house-brand generic lines of products, including over-the-counter medications. Does the marketing and selling constitute manufacturing because the products are manufactured for a specific brand? How is Mr. Shkreli supposed to determine if such a company is "primarily" involved in the manufacture, marketing and commercialization of such products? Further, the inclusion of the notice requirement in Section II.G shows that such a determination cannot be made with certainty under the terms of the Judgment. Mr. Shkreli cannot "ascertain from the four corners of the order precisely what acts are forbidden," and which are permitted. *Sanders*, 473 F.2d at 247. The Order threatens to bar him from gainful employment in areas that have no bearing on the pharmaceutical industry and the conduct at issue in this case. Therefore, this type of injunctive relief is the very type prohibited by Rule 65(d).

Accordingly, there is a "substantial possibility" that Mr. Shkreli will succeed in challenging the Court's injunction as overly broad and impermissibly vague.

2. The Court Erred in Holding that Vyera's Agreements Caused Anticompetitive Effects.

The Court erred in at least two ways in holding that Vyera's exclusive API and distribution agreements resulted in anticompetitive effects: (1) the Court failed to apply the correct legal standard in concluding that Vyera's API supply agreements were anticompetitive; and (2) the Court erred in holding that plaintiffs had met their burden of proof that the agreements at issue *caused* the alleged anticompetitive effects.

a. The Court Failed to Apply the Correct Legal Standard.

The question of the proper legal standard to apply in determining whether plaintiffs had met their burden to prove anticompetitive effects is reviewed *de novo*. *Pierce v. Underwood*, 487 U.S. 552, 558 (1988). In support of its holding that Vyera's agreements resulted in anticompetitive effects, the Court found that "Vyera's exclusive supply agreements . . . with Fukuzyu and RL Fine closed off access to the two most viable suppliers of pyrimethamine for years," and thus "delayed the entry of generic pyrimethamine." ECF 865, at pp. 111-12. Relying on *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 656 (2d Cir. 2015) ("*Actavis PLC*"), the Court stated the legal standard as follows: "[G]enerics need not be barred from all means of distribution if they are barred from the cost-efficient ones …The test is not total foreclosure, but rather whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." ECF 865, at 119. But Mr. Shkreli never argued that the test is "total foreclosure." Instead, Mr. Shkreli argued that the test for evaluating an exclusive supply agreement is "substantial foreclosure of competition in the relevant market," a test the Court never mentions despite a long line of cases on exclusive supply agreements dating back to *Tampa Elec. Co. v. Nashville Coal Co*., 365 U.S.

320, 328 (1961).[4] *See In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187, 234 (S.D.N.Y. 2019) (citation omitted) (emphasis added); *see also Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 328 (1961) (the competition foreclosed must "constitute a substantial share of the relevant market"). Plaintiffs were required to establish that Vyera's exclusive supply agreements resulted in substantial foreclosure in the global market for the pyrimethamine API used to make Daraprim. Moreover, determining "substantial foreclosure" in an API supply market requires careful analysis and consideration of the full range of potential API suppliers available to drug manufacturers, including suppliers that do not currently manufacture the specific API in question but have the capability to do so. *Fresenius Kabi USA, LLC v. ParSterile Prods., LLC*, 841 F. App'x 399, 404 n.12 (3d Cir. 2021). It must also take into account the ability of pharmaceutical companies to manufacture the API themselves. The Court declined to engage in any of this required analysis.

In *Fresenius Kabi USA, LLC*, the plaintiff alleged that the defendant—the NDA holder for an injectable blood pressure medication—violated federal and state antitrust law by entering into exclusive supply agreements with three different API suppliers, delaying the plaintiff's ability to secure a supply of API. *See id.* at 401-02. In remanding the case to the district court for further proceedings, the Third Circuit offered a number of observations on how courts should assess whether exclusive API supply agreements have the potential to substantially foreclose

[4] *Actavis PLC* is inapposite to the question of whether Vyera's exclusive supply agreements were anticompetitive. There was no exclusive supply agreement at issue in that case, which involved state generic substitution laws. Even considered more broadly on the question of possible anticompetitive effects, *Actavis PLC* is easily distinguished from this case. The court in that case engaged in a "careful consideration of the unique characteristics" of the automatic generic substitution system in the pharmaceutical industry and found that other methods of competition by generics "would be impractical and ineffective." 787 F.3d at 655. Here, by contract, the record evidence demonstrates that pyrimethamine API is easy to make, and thus generic competitors had practical and effective methods of competing with Vyera's Daraprim outside of contracting with Vyera's API suppliers, namely, contracting with other API manufacturers.

competition. First, as plaintiffs have acknowledged in this case,[5] the Third Circuit observed that exclusive API supply agreements are "fairly normal" in the pharmaceutical industry. *Id*. at 404 n.12. Second, the Third Circuit observed that the fact that other generic manufacturers worked with API suppliers other than those with which the defendant had exclusive supply agreements, and had successfully filed ANDAs, weighed against a finding of substantial foreclosure. *Id*. Third, the court noted that the district court could consider whether there were other API suppliers that were "willing to provide API," specifically including those that "either had not yet begun or were in the early stages of producing" the API in question. *Id*. Fourth, the court held that "[i]n conducting this analysis the absence or presence of a DMF is not in itself dispositive" because "[a] manufacturer need not partner with a supplier with an active DMF during its development of an ANDA, and sometimes a drug applicant may choose to not reference a DMF in its ANDA filing at all." *Id*.

The Court, in its Opinion, ignored the "substantial foreclosure of competition" standard for exclusive supply agreements and disregarded the factors set forth in *Fresenius Kabi USA, LLC*. Instead, the Court applied a lesser standard – "whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit" – that does not apply to exclusive supply agreements. Thus, an appeal is likely to succeed on the merits due to the Court's failure to address and apply this well-established legal standard.[6]

[5] *See* ECF No. 88, Tr. of Mar. 20, 2020 Pretrial Telephone Conference at 17-18 (counsel to the FTC: "It's not uncommon in the pharmaceutical industry for a branded company to enter an exclusive contract with an API supplier in order to make sure that it has adequate supply and that their interests are aligned.").

[6] Indeed, as the Supreme Court stated in *Ohio v. Am. Express Co*., 138 S. Ct. 2274, 2284 (2018), under the rule of reason analysis, "the plaintiff has the initial burden to prove that the challenged restraint has a *substantial anticompetitive effect* that harms customers in the relevant market." (emphasis added). The Court here attempted to distinguish *American Express*, *see* ECF 865 at 118, but the Supreme Court's statement in that case of the plaintiff's initial burden of proof is nearly identical to the well-recognized standard for exclusive supply agreements, as we argue here. The Court erred in failing to apply that burden here.

b. The Court Erred in Holding that Plaintiffs Had Met Their Burden to Prove Causation.

The Court also erred in holding that plaintiffs had met their burden of proving that the agreements at issue caused anticompetitive effects through a delay in the entry of generic competition, ignoring substantial record evidence that delay – if there was any – was caused by the generic pharmaceutical companies' independent business decisions and not the agreements at issue. Under the Sherman Act, the Court must find that the alleged injury was "caused" by the defendant's anticompetitive conduct. *Irvin Indus., Inc. v. Goodyear Aerospace Corp*., 974 F.2d 241, 244 (2d Cir. 1992). When an injury "[i]s attributable to . . . other factors independent of" the challenged conduct, a plaintiff has "not . . . met its burden." *Zenith Radio Corp. v. Hazeltine Research, Inc*., 395 U.S. 100, 126-27 (1969)*; see also Discover Fin. Servs. v. Visa U.S.A., Inc.,* 582 F. Supp. 2d 501, 503–04 (S.D.N.Y. 2008) ("[A] plaintiff must have proved that some damage occurred to it as a result of defendant's alleged antitrust violation, and not some other cause. . . . [I]f . . . that plaintiff's injury was caused primarily by something other than the alleged antitrust violation, . . . that plaintiff has failed to prove that it is entitled to recover damages from defendant." (quoting ABA Section of Antitrust Law, Model Jury Instructions in Civil Antitrust Cases (2005) at F-3)); *see also In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 652–53 (E.D. Mich. 2000) ("Simply put, when an independent cause fully accounts for the plaintiff's alleged antitrust injury, it breaks the causal connection between the alleged antitrust violation and the plaintiff's injury.").

As just one example, the Court failed to require plaintiffs to prove by a preponderance of the evidence that Vyera's exclusive supply agreement with Fukuzyu caused the delay in generic entry. In response to Mr. Shkreli's argument that the record evidence demonstrates that it was the generic manufacturers' own business decisions that caused any delayed entry, the Court responds,

without further analysis, "He is wrong." ECF 865, at 118. The Court acknowledges that Cerovene began developing generic Daraprim in 2013, two years before Vyera acquired Daraprim and four years before Vyera entered into its supply agreement with Fukuzyu. But the Court ignores that Cerovene's President, Mr. Shah, testified that Cerovene was unsuccessful in obtaining pyrimethamine from Fukuzyu during its attempts throughout 2015 and 2016, *before* Vyera had begun negotiations with Fukuzyu. Shah, Trial Tr. 697:8-18. Fukuzyu's unwillingness to supply Cerovene with pyrimethamine cannot be attributed to Vyera. Similarly, Fera's President, Frank Della Fera, testified that Fera first reached out to Fukuzyu in late 2015 and prior to March 2016. Fera, Trial Tr. 449:10-450:12. Fukuzyu did not respond to Fera's initial inquiries, which occurred well before Vyera had contacted Fukuzyu, and therefore Vyera's eventual supply agreement with Fukuzyu was not the cause of Fera's inability to obtain pyrimethamine from Fukuzyu. GX8007, at para. 19.

But even if the record *had* showed some causal connection between Vyera's contract with Fukuzyu and Fukuzyu's denial of API to the generic companies, the Court fails to hold plaintiffs to their burden to prove causation in fact, by ignoring the "independent causes," *i.e.*, the numerous business decisions that the generic companies made that clearly caused delay in the FDA's approval of their ANDAs for generic Daraprim. For example, the record shows that Fera expressly declined numerous opportunities to purchase Daraprim RLD, including an opportunity to purchase five bottles of Daraprim RLD, and instead chose to purchase only two bottles, which required it to request a waiver from the FDA, resulting in substantial delays. The record evidence also shows that Cerovene refused to take the advice of its more sophisticated partner, Dr. Reddy's, and obtain the requisite RLD from a procurement firm with an established relationship with Dr. Reddy's, instead trying and failing to obtain RLD from a different source. These independent business

decisions caused the delay in generic entry – not Vyera's agreements with suppliers and distributors.

3. The Court Erred in Holding Mr. Shkreli Jointly and Severally Liable.

The Court incorrectly applied the law on joint and several liability and erred in finding Mr. Shkreli jointly and severally liable for all of Vyera's "wrongful profits." In *Liu v. SEC*, the Supreme Court stated that the "common-law rule requir[es] individual liability for wrongful profits," because joint and several liability "could transform any equitable profits-focused remedy [such as disgorgement] into a penalty." *Liu v. SEC*, 140 S. Ct. 1936, 1949 (2020). The *Liu* Court stated, however, that joint and several liability may be appropriate under limited circumstances involving "partners engaged in concerted wrongdoing." *Id*. *Liu* involved two petitioners, a married couple, who were held liable for securities fraud for developing a business that solicited and funneled nearly $27 million of investor money to benefit themselves and their personal businesses. *Id*. The Court found that petitioners "diverted a sizable portion of those funds to personal accounts and to a company under [one petitioner's] control," while "[o]nly a fraction of the funds were put toward" the stated use. *Id*. The Supreme Court reversed the lower court's holding of joint and several liability and remanded the case to the Ninth Circuit to determine whether the petitioners can, based on the equitable principles and factors set forth in the Court's opinion, be found jointly and severally liable. The Court listed several exemplar factors for the lower court to use in the determination of joint and several liability in *Liu*: (1) petitioners were married; (2) petitioner Liu formed multiple business entities and solicited investments, which he personally misappropriated; (3) petitioner Wang held herself out as president and member of the management team of an entity to which Liu directed misappropriated funds; (4) both spouses

personally profited and neither were mere passive recipients of the profits; (5) petitioners' finances were commingled and both enjoyed the fruits of the scheme. *Id.*[7]

Here, none of the *Liu* factors is present, and the Court's Judgment runs afoul of the Supreme Court's warning against the imposition of joint and several liability. Unlike in *Liu*, Mr. Shkreli has received no profits from his investment in Vyera. Indeed, it is undisputed that Mr. Shkreli personally invested $18 million into Vyera and took no salary or other compensation from Vyera. Mr. Shkreli did not misappropriate any funds, and his personal investment into Vyera cannot be considered a "commingling" of funds under any logical definition of that term, particularly given that he has received no compensation or profit from Vyera.

Plaintiffs introduced no evidence that Mr. Shkreli profited one cent from the alleged anticompetitive agreements. Despite the absence of any of the equitable principles required for joint and several liability, the Court ordered Mr. Shkreli jointly and severally liable for all of Vyera's wrongful profits. ECF 865, at pp. 132-134. The Court held, without any record evidence in support, that "[a]s Vyera's founder and its largest shareholder, any excess profit gained from Shkreli's scheme directly benefited him." ECF 865, at p. 133. This vague and unsupported conclusory statement cannot serve as the basis for such a drastic remedy as joint and several liability. The only "factor" set forth in support of the Court's holding of joint and several liability is that Mr. Shkreli was the "prime mover" of the "anticompetitive scheme," which was Mr. Shkreli's "brainchild." *Id*. The Court misapplied the equitable principles set forth in *Liu* to hold

[7] The Ninth Circuit then remanded to the Central District of California, which held petitioners jointly and severally liable based on the factors set forth by the Supreme Court, including that petitioners misappropriated funds, were not "mere passive recipients of profits," their finances were "commingled" with the entities' finances, and petitioners enjoyed the "fruits of the scheme," none of which is at issue here. *Sec. & Exch. Comm'n v. Liu*, 2021 WL 2374248, at *9 (C.D. Cal. June 7, 2021).

Mr. Shkreli jointly and severally liable. Indeed, there is no record evidence to support the Court's holding.

In addition, the Court's holding of joint and several liability relies upon a case that is inapposite. The Court cites *SEC v. First Jersey Sec., Inc*., a pre-*Liu* case, in support of its joint and several liability holding. 101 F.3d 1450 (2d. Cir. 1996). The *First Jersey* court's joint and several liability holding, however, was entirely dependent upon the individual defendant's personal liability as a "controlling person under § 20(a) of the 1934 [Securities Exchange] Act" and not the equitable principles as stated in *Liu*. *Id*. at 1471.[8] Because this is not a case brought under the Securities Exchange Act of 1934 and does not rely upon the definition of a "controlling person under § 20(a) of the 1934 Act," and because *Liu* has set forth the standard for joint and several liability, the Court's reliance upon *First Jersey* for joint and several liability is misplaced. ECF 865, at pp. 132-33.

Accordingly, there is a "substantial possibility" that Mr. Shkreli will succeed in challenging the Court's order for joint and several liability.

4. <u>The Court Erred in Holding that Plaintiffs Had Met Their Burden to Prove the Relevant Product Market.</u>

The Court erred in holding that plaintiffs had met their burden to prove the relevant product market of U.S. FDA approved pyrimethamine. It is axiomatic that as an initial step, Plaintiffs "have the burden at trial of establishing the relevant product market." *Hayden Publ'g Co. v. Cox Broad. Corp.*, 730 F.2d 64, 68 (2d Cir. 1984). "The relevant market must be a market for particular products or services, the 'outer boundaries' of which 'are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and

[8] Further, in *First Jersey*, the CEO of the company was held jointly and severally liable only after he was found to have received compensation from the company and was the 100% sole owner, facts that are not present here. *Id.*

substitutes for it.'" *US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 64 (2d Cir. 2019) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962)). "'Interchangeability' looks to the use or function of the given product as compared to other products." *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 575 (S.D.N.Y. 2011) (citation omitted). "'Cross-elasticity' is related to interchangeability, and requires a consideration of the extent to which a change in the price of one product will alter demand for another product." *Id.* (citation omitted).

In the context of prescription drugs, courts assessing interchangeability look to the extent to which one drug has "similar effectiveness" and is therefore "readily substitutable" with another drug for the treatment of the underlying condition. *See, e.g.*, *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 435–36 (3d Cir. 2016) (citation omitted). The cross-elasticity analysis for prescription drugs focuses on the extent to which a change in the price of one drug (Drug X) affects the demand for that drug, as well as for other drugs (Drug Y) used to treat the same condition. *See, e.g.*, *Geneva Pharms. Tech. Corp. v. Barr Labs, Inc.,* 386 F.3d 485, 496-99 (2d Cir. 2004). If a price increase of Drug X causes sales of Drug X to decline and sales of Drug Y to increase, Drug X and Drug Y are said to show a high degree of cross-elasticity of demand, likely indicating that both Drug X and Drug Y are properly considered to be within the relevant product market. *See Mylan Pharms. Inc.*, 838 F.3d at 437.

"In considering what is the relevant market for determining the control of price and competition, no more definite rule can be declared than that commodities reasonably interchangeable by consumers for the same purposes make up that 'part of the trade of commerce', monopolization of which may be illegal." *United States v. E.I. duPont de Nemours and Co. (Cellophane)*, 351 U.S. 377, 395 (1956). "The 'market' which one must study to determine when a producer has monopoly power will vary with the part of commerce under consideration. The

tests are constant. That market is composed of products that have reasonable interchangeability for the purposes for which they are produced -- price, use and qualities considered." *Id*. at 404.

The Court erred in holding that plaintiffs had met their burden to establish the relevant product market. Neither "reasonable interchangeability of use" nor "cross-elasticity of demand" support plaintiffs' proposed relevant product market. The evidence presented at trial is uncontroverted that TMP-SMX, Atovoquone, and compounded pyrimethamine are medical alternatives for treating patients with active toxoplasmosis and for prophylaxis. Every piece of evidence at trial showing decision-making of actual physicians supports the conclusion that all of these alternative therapies are within the proper standard of care, as explained by plaintiffs' own expert, Dr. Hardy. The fact that FDA-approved pyrimethamine is the gold standard for active toxoplasmosis and that TMP-SMX is the gold standard for toxoplasmosis prophylaxis only shows that these alternative treatments are better options for certain patients—not that they are each their own relevant product market. Moreover, plaintiffs' own economic expert, Professor Hemphill, admitted that he did not have quantity and price data for TMP-SMX, Atovoquone, or compounded pyrimethamine to determine the cross-elasticity of demand, which is necessary to establish a relevant product market. Moreover, Professor Hemphill acknowledged that at least some of Daraprim's significant "quantity loss [after the 2015 price increase] is plausibly attributable to consumers switching to [Bactrim] or compounded pyrimethamine." (Hemphill Report ¶ 138).

Accordingly, plaintiffs failed to prove their proposed relevant product market. Mr. Shkreli is likely to succeed on the merits of his challenge to the Court's holding on relevant market.

C. Mr. Shkreli Will Suffer Irreparable Harm Absent a Stay of the Judgment

Absent a stay of the Court's Judgment, Mr. Shkreli will suffer irreparable harm by losing the opportunity to reintegrate into society by working in the industry in which he has specialized knowledge, and by losing his First Amendment rights. To establish irreparable harm, the party

seeking the stay has the burden of showing "injury that is not remote or speculative but actual and imminent, and for which a monetary award cannot be adequate compensation." *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 108, 123 (S.D.N.Y. 2012). With respect to the restraint on Mr. Shkreli's ability to be employed by a Pharmaceutical Company, although the "loss of employment 'does not *usually* constitute irreparable injury,'" the Second Circuit has held that it does in "unusual case[s]" and even in preliminary injunction cases. *Kane v. De Blasio*, Nos. 21-2678, 21-2711, 2021 U.S. App. LEXIS 35102, at *26 n.18 (2d Cir. Nov. 28, 2021) (internal citation omitted) (collecting cases finding loss of employment to constitute irreparable injury). In *Kane*, the Court held that loss of employment constituted irreparable injury where the enjoined party "demonstrated a likely violation of [his or her] First Amendment rights." *Id.*

This is certainly not a *usual* case involving loss of employment.[9] This is not a labor and employment case, such as a non-competition or trade secrets case, where an individual may be restrained from working for a competitor, or in a specific position, for a short period of time.[10] Nor is this a case involving fraud and consumer protection laws, where courts have upheld industry bans. This is the first time the FTC has sought and obtained an industry ban against an individual in an antitrust case. Moreover, the ban is particularly far-reaching, banning Mr. Shkreli ***for life*** from "***directly or indirectly participating*** in any manner in the pharmaceutical industry." This case, and the ban, are unusual.

Since 2004, Mr. Shkreli's career, either as an investment manager or as a founder, has been focused on the pharmaceutical industry. In addition to investing in, founding and working for new

[9] Indeed, research has failed to reveal such a draconian injunction to cite in comparison.

[10] *See Sunbelt Rentals, Inc. v. Love*, No. 20-17611 (RMB/AMD), 2021 U.S. Dist. LEXIS 107895, at *17 (D.N.J. June 9, 2021) (finding no irreparable harm because the loss of employment was "with a particular employer" and was "temporary," as opposed to a "permanent loss of job[]").

pharmaceutical companies, Mr. Shkreli has gainfully contributed to medical science by researching and developing new drugs to treat rare diseases such as Duchene Muscular Dystrophy ("DMD") for which Mr. Shkreli wrote the genetic sequence for recombinant dystrophin, hoping that it could one day be used to help people suffering from muscular dystrophy, and pantothenate kinase-associated neurodegeneration, or "PKAN," in which Mr. Shkreli obtained a patent for the novel treatment he co-invented. Thus, to ban Mr. Shkreli from participating in the pharmaceutical industry–an industry to which he has devoted a substantial period of his life–would cause him irreparable harm. *See Goldhaber v. Foley*, 519 F. Supp. 466, 475 (E.D. Pa. 1981) (finding irreparable harm where enjoined parties "have been employed as court reporters in the bankruptcy court for a considerable period of time. To remove them from their established careers and force them to seek new employment would constitute irreparable injury, even assuming that they had available a cause of action for damages which would recompense them for any pecuniary loss.").

In addition, as in *Kane*, the Court's Judgment necessarily restrains Mr. Shkreli's exercise of his First Amendment rights. Section II.B of the Judgment forbids Mr. Shkreli from "[p]articipating in the formulation, determination, or direction of any business decisions of any Pharmaceutical Company." Because this restraint is so vague, it potentially sweeps in conduct that would have no effect on competition in the pharmaceutical industry. For example, if a friend who happens to work in the pharmaceutical industry asks Mr. Shkreli a question that relates to a business decision or the manufacture of a Drug Product, would exercising his First Amendment right by answering the question violate the injunction?

Similarly, Section II.D of the Judgment prohibits Mr. Shkreli from "[t]aking any action to directly or indirectly influence or control the management or business of any Pharmaceutical Company; Shkreli's public statements about a Pharmaceutical Company will be deemed an action

taken to influence or control the management or business of any Pharmaceutical Company if Shkreli intended the statement to have that effect or if a reasonable person would conclude that the statement has that effect;." When Mr. Shkreli raised First Amendment concerns regarding this provision, the Court held that Mr. "***Shkreli's violations of the antitrust laws have lost for him the right to speak publicly about the pharmaceutical industry*** when such speech is uttered to influence the management or business of a Pharmaceutical Company," even if he has no ownership, employment, or other interest whatsoever in that company. ECF No. 875 at p. 8 (emphasis added). The Court's ruling on this issue is simply an unnecessary and punitive restriction of his First Amendment rights, preventing him from publicly discussing potential cures for a range of diseases in which he has an interest. Even if he has no intent to influence the management or business of a pharmaceutical company, he runs the risk of violating this provision by making any public statements involving the industry lest his statement be deemed as having that intent. This example highlights the impropriety of going beyond barring Mr. Shkreli from participating in two specific types of anticompetitive agreements to banning Mr. Shkreli for life from publicly discussing or participating in any aspect of the pharmaceutical industry. There is simply no support for such a far-reaching ban in case law, statute, or the United States Constitution.[11]

In addition, the Court's Order requires Mr. Shkreli to divest his shares in Vyera within 180 days, if the receiver appointed in *Koestler v. Shkreli*, 1:16-cv-7175 (S.D.N.Y.) returns any of Mr. Shkreli's shares to him. A required divestiture of property cannot be undone if he is successful on

[11] The Court attempts to support its restraint on Mr. Shkreli's First Amendment rights by citing a case in which an individual was banned from "trying to intimidate . . . with threats of spurious lawsuits" specific individuals at a specific company. *See* ECF No. 875 at p. 8, citing *Peregrine Myanmar v. Segal*, 89 F.3d 41, 49 (2d Cir. 1996). Although the Court characterized that case as one where the injunction "restrain[ed] the defendant from communicating with the management of a joint venture," the injunction in that case was far more limited than the overbroad injunction that the Court issued against Mr. Shkreli.

appeal. Courts have acknowledged that a divestiture of property can constitute irreparable harm. *See Flowers Indus. v. FTC*, 849 F.2d 551, 552 (11th Cir. 1988). Should Mr. Shkreli succeed on appeal, his shares in Vyera will not be returned to him, and monetary relief cannot replicate or repair his loss of property – this is textbook irreparable harm.

In short, the restraints on Mr. Shkreli's employment and exercise of his First Amendment rights in the Court's Judgment, as well as his loss of property, constitute irreparable harm if a stay is not granted.

D. Issuance of the Stay Will Not Substantially Injure Any Interested Parties

The issuance of a stay will not substantially injure any interested parties. The Court held that Mr. Shkreli engaged in specific anticompetitive conduct through Vyera, *i.e.*, exclusive supply and specialty distribution agreements, for a specific drug, Daraprim. There is little risk of Mr. Shkreli engaging in that conduct during the pendency of the stay. Vyera has entered into a settlement agreement that prohibits it from entering into these types of agreements. ECF 754, at pp. 6-7. And Vyera's settlement agreement prohibits it from "appoint[ing] as an officer or director, or otherwise do[ing] business with Defendant Martin Shkreli." *Id*.

Additionally, the CREATES Act, enacted in December of 2019, creates a private right of action – where none existed before – for generic drug manufacturers to obtain an injunction against a branded pharmaceutical company that refuses to sell samples of the reference listed drug, or RLD, on a timely and commercially reasonable basis. The CREATES Act places legal restrictions on the precise conduct the Court's Order enjoins. 21 U.S.C. § 355-2.. Plaintiffs have not shown that there is a threat of substantial injury to interested parties outside of the conduct at issue in this case, which has been halted by Vyera's settlement agreement and the CREATES Act. Accordingly, the issuance of a stay will not substantially injure any interested parties.

E. The Public Interest Will Be Served By Granting the Stay

If the stay is granted, Mr. Shkreli will be permitted to return to researching and developing life-saving drugs for patients suffering from rare diseases such as DMD and PKAN, during the pendency of the appeal. Without a stay, Mr. Shkreli will be prohibited from participating in such research and development, regardless of how unrelated it may be to the commercial aspects of the pharmaceutical industry. Mr. Shkreli has always had a passion for finding cures for rare diseases, and spent years after college studying drug trials, chemistry, and has devised the novel treatments for DMD and PKAN discussed above. Mr. Shkreli's abilities and desire to develop such drugs serves the public interest. Thus, the public interest is served by staying the injunction entered by the Court and permitting Mr. Shkreli, upon his release from prison and reentry into society, to continue pursuing his interest and utilizing his specialized skills and knowledge in the healthcare field and the development of life-saving treatments.

Additionally, the public interest will be served by staying an injunction that is overly broad, punitive, and chills First Amendment rights. *See, e.g., Am. Patriot Express v. City of Glens Falls*, No. 1:20-CV-0672 (LEK/CFH), 2020 U.S. Dist. LEXIS 170902, at *22 (N.D.N.Y. Sep. 18, 2020) ("[I]t is always in the public interest to protect First Amendment liberties. . . . Normally, the Court would assume that the interests of the government are aligned with the public interest, but that is not so when the government violates an individual's First Amendment rights."); *Am. Freedom Def. Initiative v. Metro. Transp. Auth.*, 70 F. Supp. 3d 572, 584 (S.D.N.Y. 2015) (holding that even "threat[s] posed by terrorism" "do not outweigh the public interest in protecting First Amendment rights").

F. At a Minimum, the Court Should Modify the Preliminary Injunction Pending Appeal

Should the Court decide not to stay the injunction pending appeal, it should at least modify the injunction's scope. *See* Fed. R. Civ. P. 62(d) (authorizing courts to "modify" an injunction pending appeal). The same four factors govern requests to stay and modify injunctions pending appeal. *FN Herstal, S.A. v. Clyde Armory, Inc.*, No. 12-cv-102, 2016 WL 5422073, at *5 (M.D. Ga. Sept. 27, 2016); *see also Century 21 Real Estate LLC v. All Professional Realty, Inc.*, 899 F. Supp. 2d 1198, 1243–44 (E.D. Cal. Aug. 8, 2012) (analyzing motions to stay and modify under same standard). For the reasons set forth above, should the Court decide not to stay the injunction pending appeal, it should at least modify the injunction by narrowing it to merely a prohibition on Mr. Shkreli entering into any exclusive supply or limited distribution agreements in the United States pharmaceutical industry pending appeal.

IV. CONCLUSION

For all of the foregoing reasons, Mr. Shkreli's motion to stay the Final Judgment pending his appeal should be granted.

Dated: March 7, 2022

Respectfully submitted,

By: */s/ Christopher H. Casey*

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CERTIFICATE OF SERVICE

I certify that on March 7, 2022 a copy of the foregoing was served upon all counsel of record in this matter using the Court's CM/ECF system.

/s/Andrew J. Rudowitz